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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/550,605 04/17/00 ANDERSSON

L 064727.0109

EXAMINER

026118 HM12/0312
BROBECK, PHLEGER & HARRISON, LLP
ATTN: INTELLECTUAL PROPERTY DEPARTMENT
1333 H STREET, N.W.
WASHINGTON DC 20005

ART UNIT	PAPER NUMBER
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1655
DATE MAILED:

03/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/550,605

Applicant(s)
Andersson et al

Examiner
Jehanne Souaya

Group Art Unit
1655



☒ Responsive to communication(s) filed on Apr 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Nucleotide Sequences

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, the specification and the claims contain nucleic acid sequences that are not designated by SEQ ID NO. Applicant is requested to return a copy of the attached Notice to Comply with the response. A response missing a CRF will be considered "non responsive".

Claim Rejections - 35 USC § 112

Written Description

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1,4,5,8,10-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to determining coat color genotype in a pig comprising analyzing a nucleic acid sample to determine whether a mutation is or is not present at one or more exon/intron splice sites of the KIT gene (claims 1,4,5,8 and 10-13), or whether a splice variant protein is present (claim 14). The specification teaches that an alteration of the 5' intron splice site of intron 17 of the KIT2 gene is associated with the white coat color of pigs. The specification teaches that the alteration is from a GT pair to an AT pair which affects the splicing of the pre mRNA and results in the loss of the whole of exon 17 from the mRNA transcribed from the I-KIT2 sequence. The specification, however fails to teach genotyping by analyzing mutations in any other exon/intron splice sites of either KIT1 or KIT2. The KIT gene has at least 19 exons (see Moller), therefore there are at least 38 exon/intron splice sites (5' and 3' of the intron), 37 of which has applicant's have not characterized or analyzed in terms of genotyping the coat color of a pig. The specification fails to describe a representative number of the various substitutions, insertions, deletions or frameshift mutations that are encompassed by the claims. Furthermore, applicant's have not taught splice variant proteins that would result from these mutations. Each of the claimed inventions is a genus for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description much convey to one of skill int he art "with reasonable clarity" that as of the

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filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of genotypes corresponding to mutations at exon/intron boundaries of the KIT gene and how these effect the coat color of a pig, the specification fails to show that applicant was in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Indefinite

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 14 are indefinite because the claims fail to include a positive process step relating back to the preamble. The preamble states a method for determining the coat color genotype of a pig but the final process step is analyzing nucleic acid. Therefore the method is unclear as to whether it is to a method of genotyping or to a method of analyzing nucleic acids. For claim 14, the preamble states determining the coat color genotype of a pig but the final process step is determining whether the protein is the splice variant protein. Therefore it is unclear whether it directed to a method of genotyping or to a method of analyzing a protein.

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Claims 1 and 15 are indefinite as it is which side of an intron is encompassed by the language "exon/intron boundary". For example, does this refer only to boundaries of an exon followed by an intron (5' of the intron), ie: boundary of exon 17 and intron 17, or does it also include the boundary of intron 17 and exon 18 (3' of intron), intron 1 and exon 2, intron 2 and exon 3, etc...

Claim 3 is in improper form. It recites "A method *is* claimed..." instead of -- A method *as* claimed...--

Claim 5 is indefinite in the recitation of "nucleic acid genomic DNA". It appears that applicant has omitted the word "is" between "acid" and "genomic".

The term "the splice variant protein" in claim 14 lacks proper antecedent basis as it is unclear what "splice variant protein" is being referred to.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 15 is rejected under 35 U.S.C. 102(a) as being anticipated by Moller et al., (Mammalian Genome, 1996, vol. 7, pp 822-830).

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Claim 15 is drawn to a kit comprising one or more reagent suitable for determining whether a mutation is present at one or more intron/exon splice sites of the KIT gene. Such a kit reads on nucleic acid primers that will amplify a fragment of the KIT gene between any exon/intron boundaries of the KIT gene. Moller (1996) teaches amplifying a 180 base pair fragment consisting of part of exon 18/intron18/part of exon 19. Thus Moller inherently teaches reagents which anticipate claim 15. As a kit carries no patentable weight, such primers read on claim 15 regardless of why they were designed.

7. No claims are allowable.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Patent examiner
March 8, 2001

W. Gary Jones
W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
3/9/01